Cargill Supplier and External Manufacturer Qualification Requirements for Second and Third Party Laboratories

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NOTE TO OUR SUPPLIERS AND EXTERNAL MANUFACTURERS

I am pleased to introduce Cargill's Second and Third Party Laboratory Qualification Requirements Process Manual.

Cargill is committed to providing healthy, nutritional food/feed products and services throughout our supply chain. To fulfill this commitment, every day we make critical decisions based on data from testing results generated across the supply chain. This is why the effort to consistently generate valid, accurate, and credible results is so important and your role, as a reliable partner, is critical to make it possible.

As we continue to work to mitigate food and feed safety risks, reduce quality risks, and keep people and animals safe, we will only work with those laboratory service providers that ensure the accuracy and credibility of the data they produce.

We know this is not always an easy journey, so on behalf of Cargill I want to thank you for your continuing hard work and contribution to ensuring the delivery of high quality data as we work to provide high quality, safe food, every time, everywhere.

Sincerely,

Mike Robach
VP, Corporate Food Safety, Quality and Regulatory
Cargill, Incorporated

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Introduction

Cargill is an international producer and marketer of food, agricultural, financial and industrial products and services. Cargill helps customers succeed through collaboration and innovation, and is committed to applying its global knowledge and experience to help meet economic, environmental and social challenges wherever it does business. In light of its geographic, cultural, economic, and regulatory diversity and mission, Cargill has set global food and feed safety, quality and regulatory processes and standards to ensure the consistency and integrity of all of our products and services.

Cargill's mission and food/feed safety policy reflect a core value for Cargill – nourishing people and ensuring that our food and feed products keep people and animals safe. We have complex supply chains, a global footprint that requires full cooperation and support from our suppliers and external manufacturers (S/EMs), and customers focused on food/feed safety that expect us to do same with our S/EMs. This requires Cargill to ensure our S/EMs are aligned with our values and operate in full compliance with Cargill's food/feed safety, quality and regulatory requirements.

In 2011, Cargill began deploying one global consistent process for qualifying suppliers and external manufacturers. It is called the Supplier and External Manufacturer Management Process or S/EM Process. A major goal of the process is to enable Cargill to qualify suppliers that

are capable of meeting all the requirements of our many business units and reduce redundant requalification by multiple businesses. The current scope of the S/EM Process includes food/feed ingredients, food/feed processing aids, food/feed contact chemicals, food/feed contact packaging, and all materials produced on behalf of Cargill by External Manufacturers as well as laboratory services.

This manual is designed for use by our laboratory service suppliers and provides information on Cargill's compliance qualification and management process for second and third party laboratories.

Cargill Food/Feed Safety, Quality and Regulatory Requirements

There are three basic components to Cargill's Food/Feed Safety, Quality and Regulatory Requirements: (i) Legal and Regulatory Requirements, (ii) Codex Prerequisite Programs and HACCP and (iii) Cargill Specific Requirements.

A Good Laboratory Practices (GLPs) / Laboratory Quality Program is recognized as an important element of Prerequisite Programs that make up an overall Food Safety / Quality program.

Good Laboratory Practices: Systems must be in place to ensure reliability of laboratory results for testing done on products or materials manufactured for Cargill. This includes use of recognized test methods, documented procedures, trained and competent analysts, calibrated and maintained equipment.

Qualification of Second and Third Party Laboratories

Cargill's qualification process of second and third party laboratories has three main components: (i) RFi, (ii) Determination of Overall Risk Profile and corresponding Due Diligence, (iii) Determination of Laboratory Approval Status.

A. REQUEST FOR INFORMATION (RFI)

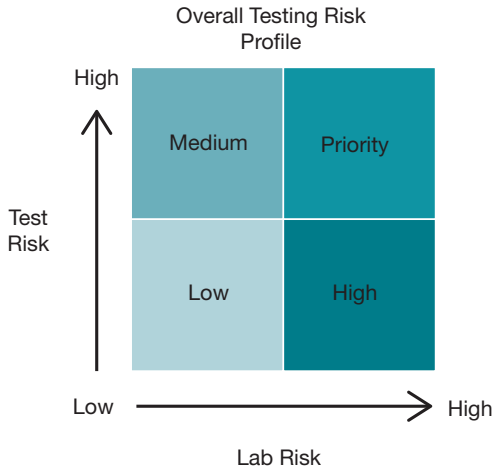
Each prospective laboratory is pre-screened with a Request for Information (RFi). Common elements asked for as part of the request:

- Confidentiality Agreement
- Laboratory Questionnaire focusing on aspects of the laboratory's quality system
- Methods, detection levels of test(s) in question
- Accreditation / certification scopes
- Price list / payment options
- Turnaround time
- Reporting options
- Sample processing and disposal
- Subcontracting process
- Supporting documents

This information is uploaded into Ariba (Cargill Global Sourcing system for contract management) and Archer (Cargill database) by prospective laboratories. This step is only done once per laboratory location. The laboratory's standard response form is considered an acceptable response provided it encompasses all the requested information.

B. DETERMINATION OF OVERALL RISK PROFILE

Each laboratory questionnaire is reviewed by Cargill's Laboratory Qualification Team. The team will use the questionnaire and RFi responses to help determine laboratory risk. This, combined with risk assessments of the test(s) to be performed at the laboratory, helps determine an overall risk profile of each laboratory. This risk profile is used to determine the due diligence needed in qualifying and maintaining a working relationship with the laboratory.

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During the qualification process, an audit or targeted visit may be necessary. In this instance, Cargill will send a Cargill Qualified Laboratory Auditor to the laboratory to complete a GLP/Laboratory Quality Assessment or to review an equivalent assessment (i.e., ISO 17025).

If Cargill identifies any gaps during the audit/review process, the Laboratory must work with the Cargill Qualified Laboratory Auditor to put a corrective action plan in place. It is necessary for a corrective action plan to be completed prior to an approval status being assigned.

C. DETERMINATION OF INITIAL APPROVAL STATUS

The Laboratory Qualification Team determines the approval status of the laboratory by reviewing RFi, audit results (including corrective actions), and any documentation gathered during the qualification process. Note: This is a Laboratory Approval Status ONLY. It does not guarantee the laboratory has been awarded business with Cargill. Classifications include Approved, Approved with Conditions, Not Approved, or Disqualified. Approval status will be specific to a laboratory location.

The descriptions of Cargill's classifications are as follows:

Approved: This status represents a laboratory that has no major non-conformance(s) in its audit. There may be some minor non-conformance(s) to address. An action plan is developed with verification at next audit. The laboratory provides evidence of compliance. To stay in the "Approved" status, a laboratory must ensure all documentation is updated per plan, meets all continuing requirements, such as performance results in testing results, quality and service, and has not resulted in any unresolved issue from triggering events. When a laboratory moves from "Not Approved" to "Approved" or "Approved with Conditions", only testing performed after the date of status change may be used.

Approved with conditions: There are no critical major non-conformance(s) but there are some minor non-conformances recorded in the audit. An action plan has been developed to address the non-conformance(s) with agreed upon timeline for implementation and the laboratory provides evidence of compliance before agreed upon deadline. A Cargill follow up could include a site visit. In some cases, the laboratory may be used prior to completion and verification of corrective action with additional measures in place. In most cases, it is expected that the laboratory will be able to provide adequate documentation to assure corrective action has been fully completed without a site visit. There may also be conditions related to side-by-side testing comparisons and/or customer acceptance. To stay in this status or be eligible to upgrade to "Approved", a laboratory must ensure all documentation is updated per plan, meets all continuing requirements, such as performance results in testing, quality and service, and has not caused any lasting negative triggering events. Not meeting a deadline or failing to provide satisfactory evidence moves a laboratory to "Not Approved." When a laboratory moves from "Not Approved" to "Approved" or "Approved with Conditions", only testing performed after the date of status change may be used.

Not approved: There are two or more major non-conformances recorded in the audit. The laboratory must submit a corrective action plan for approval by Cargill. Re-audit will be conducted when corrective action plan is fully implemented and verified as effective. Major non-conformance(s) must be corrected within two months and minor non-conformance(s) must be corrected within six months. A laboratory may be moved to this status from "Approved" or "Approved with Conditions" due to a lasting negative triggering event. Cargill is not allowed to use any testing results from this laboratory until agreed upon corrective action is completed and validated. When a laboratory moves from "Not Approved" to "Approved" or "Approved with Conditions", only testing performed after the date of status change may be used.

Disqualified: Cargill may not use laboratories that are in "Disqualified" status. In this status, major non-conformances have been recorded and the laboratory has indicated they are not interested in correcting the non-conformance. Laboratories assigned this status are not allowed to re-apply to provide testing results for Cargill for at least one year and must be reviewed through Governance Process as part of re-qualification. If a laboratory is disqualified and passes governance review, they must complete all steps of the qualification process.


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Management of Second and Third Party Laboratories

Cargill's ongoing management of second and third party laboratories has four main components: (i) monitoring performance, (ii) triggering event management, (iii) approval status verification, and (iv) changes in approval status.

A. MONITORING PERFORMANCE

A monitoring process, to be defined by the contract or compliance agreement, shall be in place to evaluate laboratory performance. The process shall consist of clearly identified metrics and documented review. Examples of monitoring parameters include, but are not limited to:

- Specific documents (Audits, MSDS, etc.)
- Quality Test Data
- Performance Verification data (round robin, ring test, proficiency samples, etc.)
- Service Level Performance
- Management of Change
- Communications/Access/ Controls
- Score-carding (on-time delivery, complete)
- Control charts (Target / Range)
- Complaints / incidents
- Key Process Indicators (KPI's)

B. TRIGGERING EVENT MANAGEMENT

A triggering event is defined as an item or action that would cause Cargill to review the approval status of a laboratory. Triggering events apply to both laboratories and their subcontractors. There can be positive, negative or neutral triggers. All triggering events will be reviewed by Cargill. Examples of these events include, but are not limited to, the following:

- Audit cycle
- Cargill finished product retrieval incidents
- Laboratory recall
- Testing Kit recall
- Laboratory-specific testing incident
- Plant, ingredient or process change at Cargill
- Method, instrument, or management personnel change at the laboratory
- Industry/media events
- Regulatory enforcement
- Regulatory change
- Documentation update/Renewal not received
- Cargill-driven change
- Trends in Key Performance Indicators
- Breach of Contract/Compliance Agreement or Cargill Code of Conduct/Guiding Principles
- Audit results
- Laboratory or Facility management change
- Ownership or financial change
- Action by a Cargill customer against a Cargill vendor or vendor subcontractor
- Failure to implement Corrective Action
- Accreditation or certificate changes
- Proficiency testing failures
- Subcontracting changes

When a triggering event occurs, Cargill will have a process in place to identify and take appropriate action to complete and review laboratory approval status. Examples of these actions include, but are not limited to, the following:

- Conduct an audit, targeted visit or site visit
- Test/methodology review
- Request for information from suppliers (RFi)
- Status change up to, and including, Disqualify
- Communicate with laboratory
- Root Cause Analysis
- Increase or decrease monitoring (Probation)
- Recognition
- Reassess the risk profile of laboratory

C. APPROVAL STATUS VERIFICATION

Periodic review will be conducted based on approval status of the laboratory. At a minimum, the following are required:

Approved: Laboratories are audited no more than once per year by Cargill.

- Medium Risk – annual review of the laboratory audit summary with corrective actions. Targeted visits will take place, at a minimum, every two years.
- Low Risk – annual review of the laboratory audit summary with corrective action provided. At a minimum, a targeted visit or audit frequency of 3 years unless triggering event occurs.


ISO 9001

Approved with Conditions: It is not intended for laboratories to stay in "Approved with Conditions" status. Either their risk rating will be reviewed and moved to "Not Approved" until they have implemented satisfactory corrective actions OR Cargill will implement actions to mitigate the deficiencies that are preventing the laboratory from moving to "Approved" status. Laboratories should not remain in "Approved with Conditions" status for more than 6 months at any given risk level.

- High Risk – an audit of the laboratory with documentation of any corrective actions, Cargill targeted visits are required at the designated 6 months period.

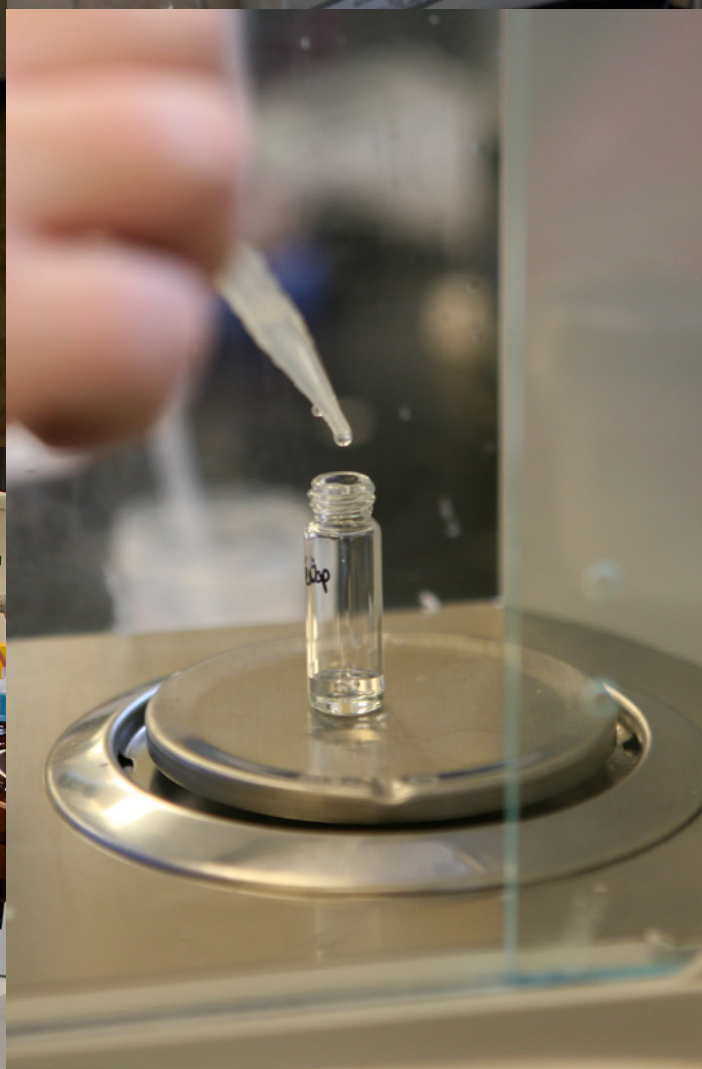
D. CHANGES IN APPROVAL STATUS

Any change in approval status, and the implications of that change, will be communicated to the laboratory. For example: Laboratories previously in "Approved" or "Approved with Conditions" status that are moved to "Not Approved" will have usage of their tests suspended until corrective action is verified and accepted . "Not Approved" laboratories cannot be used until corrective action is verified and accepted. Cargill will inform the laboratory of their status.

Variances

In rare cases, Cargill may permit second and/or third party laboratories to deviate from one or more of the Laboratory Supplier and External Manufacturer requirements. Any such deviations must be approved by Cargill, in writing.


FIRE EXIT



Glossary of Terms

Approval Status – A status assigned to each test and laboratory based on the results of their risk assessment, subsequent due diligence, corrective action and ability to meet Cargill's testing requirements. There are four possible status designations (more detail is provided in manual): Approved, Approved with Conditions, Not Approved, and Disqualified.

Archer – The technical information management system (TIMS) that is used to store supplier and external manufacturer (including laboratory) documents and information.

Audit – A documented inspection or examination of facilities, processes, programs, materials, and/or documentation. For the purposes of this manual, the term "audit" will always refer to GLP/Laboratory Quality System audit. An audit may be completed by either qualified Cargill employees or approved external parties. Verify compliance with requirements of a specific system.

Corrective Action – An action that eliminates the cause of a detected nonconformity or other undesirable situation. Typically requires a root cause analysis. NOTE: There can be more than one cause for nonconformity.

External Manufacturer – An External Manufacturer (Ex-Man) is a non-Cargill facility that "processes" and provides a "finished product" that (i) is sold under a Cargill or customer brand and/or (ii) is produced using a Cargill or customer specified process/recipe/specifications. A vendor who supplies a finished product to Cargill.

GLP (not to be confused with cGLP) – Good Laboratory Practices. A set of guidelines that is required for any internal or external laboratory that performs testing for Cargill.

Laboratory Qualification Team – The cross-functional team which determines the inherent risk of testing at a laboratory location; makes decisions on approval status, use of laboratories and the corresponding management approach based on the associated risk. The team utilizes tools developed to assess risk in tests and laboratories (Lab RAT I & II) as well as other documentation provided by the laboratory.

Request for Information (RFi) – A Request for (specific) information from a laboratory. The RFi questionnaire (Lab RAT II) is developed from stakeholder requirements.

Request for Proposal (RFp) – the actual bid solicitation process where a select group of suppliers are asked to put forth a proposal based on the key value levers of the sourcing event.

Third party laboratories – Any laboratory that is contracted or designated by Cargill to perform quality, food safety, nutritional, R&D, and government/regulatory testing and is not owned by Cargill or considered a second party lab. A type of supplier.

Triggering Event – An item or action that would cause one to review the approval status of a laboratory. A triggering event can be positive or negative.

Verification – Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

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